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510(k) Summary
for the Tiger Headless Cannulated Screws

In accordance with 21 CFR 807.92 of the Federal Code of Regulations the following 510(k) summary is submitted for the Tiger Headless Cannulated Screws

1. GENERAL INFORMATION

Date Prepared: September 14, 2011

Trade Name: Tiger Headless Cannulated Screws

Common Name: Bone Screw

Classification Name: Smooth & threaded metallic bone fixation fasteners

Class: II

Product Code: HWC

CFR section: 21 CFR section 888.3040

Device panel: Orthopedic

Legally Marketed Predicate Device: Tiger Cannulated screws (K081510)
2.4 and 3.0mm Headless Compression Screws (K050636/K021556)

Submitter: Trilliant Surgical LTD
602 Sawyer Street, Suite 120
Houston, TX 77007
Telephone: 214-288-1035

Contact: J.D. Webb
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2. DEVICE DESCRIPTION

Tiger Headless Cannulated Screws are headless, cannulated, self-drilling, self-tapping screws for the management of small bone orthopedic osteotomies and trauma. The system consists of multiple screw lengths and diameters and the necessary instruments to facilitate the placement of these implants.

Change from Predicate:
The change from the predicate device is a dimensional and geometry change.

Materials:
Ti-6Al-4V alloy per ASTM F136

Function:
The Tiger Headless Cannulated Screws are used to reduce and hold in place bone fragments, and are tightened to further compress the fragments and hold the reduction.

3. SUBSTANTIAL EQUIVALENCE CLAIMED TO PREDICATE DEVICES

The Tiger Headless Cannulated Screws are substantially equivalent to the predicate devices in terms of intended use, design, materials used, mechanical safety and performances.

4. **INTENDED USE**
   The Tiger Headless Cannulated Screws are intended for fixation of fractures, non-unions, arthrodeses and osteotomies of the small bones In the hand and foot.

5. **NON-CLINICAL TEST SUMMARY**
   The components were subjected to static axial pull out testing, static axial pull through testing, driving torque and failure torque.
   The results of this testing indicate that the Tiger Headless Cannulated Screws are equivalent to the predicate devices.

6. **CLINICAL TEST SUMMARY**
   No clinical studies were performed

7. **CONCLUSIONS NONCLINICAL AND CLINICAL**
   The Tiger Headless Cannulated Screws are substantially equivalent to the predicate devices in terms of indications for use, design, material, performance and function.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

OCT 2 0 2011

Trilliant Surgical LTD
% J.D. Webb
1001 Oakwood Blvd
Round Rock, TX 78681

Re: K112737
Trade/Device Name: Tiger Headless Cannulated Screws
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth & threaded metallic bone fixation fasteners
Regulatory Class: II
Product Code: HWC
Dated: September 14th, 2011
Received: September 20th, 2011

Dear Mr. Webb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K112737

Device Name: Tiger Headless Cannulated Screws

Indications for Use:

The Tiger Headless Cannulated Screws are intended for fixation of fractures, non-unions, arthrodeses and osteotomies of the small bones In the hand and foot.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112737